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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,217	09/21/1999	Jean-Luc Dubois	146.1307	2613

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/202,217	DUBOIS, JEAN-LUC	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *26-30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/09/1998*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's IDS, filed 12/09/2005; and election and request for extension of time, both filed 04/13/2005.

Response to Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-25 and 31, in the reply filed on 04/13/2005 is acknowledged. The traversal is on the ground(s) that groups I and II should be examined in the same application because they are relating to product and process claims. It is deemed that the claims 26 to 30 which are drawn to the manufacture of the adhesive matrix of claims 1-25 and 31 and should be properly joined together since they are of the same scope. This is not found persuasive because the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, but are extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 26-30 and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim.

Claims 1-25, and 31 are included in the prosecution.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-25 and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-21 of copending Application No. 09/194,996. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the potentially conflicted claims are directed to transdermal device to deliver progesterone and estrogen in two different compartments. The conflicted claims of application 09/194,996 anticipate the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. The use of the trademarks: "Trimegestone", "Gelva", "BIO PSA", "Scotchpak", "Hostaphan RN", "Kollidon", "Citiol", "Akrosil", and "Premarin" have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

8. Claims 20-23 and 25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-25 and 31, the claims contain the trademark/trade name "Trimegestone" and "Premarin" in claim 17. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim's scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademarks/trade name is used to identify/describe steroid sex hormones and, accordingly, the identification/description is indefinite.

Regarding claims 17 and 24, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 4, 5, 7, 8, 10, and 11, the claims recite the relative expressions "medium instant adhesive power", "strong instant adhesive power", "medium adhesive power" and "strong adhesive power" wherein expressions do not set forth the metes and bounds of the claims. Recourse to the specification does not define the expressions. Clarification is requested.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,273,772 ('771) in view of US 5,064,654 (654).

US '771 teaches Trimegestone to be delivered topically to the skin (col.4, lines 34-36, 58; col.5, lines 46-49). Trimegestone is useful to treat dysmenorrheal, sterility, ovarian dystrophia, and uterine tumors and useful as contraceptive (col.4, lines 45-49).

US '771 does not teach the silicone matrix to deliver the progesterone drug, or a structured device to deliver it.

US '654 teaches transdermal device to provide enhanced drugs flux and meanwhile is well tolerated (abstract; col.2, lines 15-23). The device comprises progesterone in a silicone matrix, and further comprises silicone fluid (col.4, lines 48, 66-68; col.5, lines 25-31; col.10, example 1). The device comprises backing layer, a membrane layer and skin contact adhesive layer (col.3, lines 29-30; col.7, lines 37-43).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver Trimegestone topically as disclosed by US '771, and select the silicone matrix and the device described in US '654 motivated by the teaching

of US '654 that the silicone matrix provides enhanced drugs flux and meanwhile is well tolerated, with reasonable expectation of having a matrix comprising Trimegestone and silicone that deliver the drug to the skin at enhanced flux and meanwhile is tolerated by the user.

13. Claims 1-19 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view US '654 and further of US 5,904,931 ('931) in view of US '771.

US '931 teaches a transdermal therapeutic system for administering a mixture of steroid sex hormones (abstract; col.4, lines 2-4). The system comprises two active ingredients containing matrix layers arranged side by side wherein one matrix is loaded with progesterone and the other is loaded with estrogen (col.6, lines 1-3, 28-32; col.8, example 4). Examples of estrogen include ethinyl estradiol (col.1, lines 27-35; col.12, line 31). The two matrices are separated by space and care must be taken for sufficient spacing of the areas to prevent a diffusion of active ingredient in the respective other area (col.6, lines 36-39). Each matrix is covered by a separate cover layer and the system as a whole is covered by a removable protective layer (Figure 2, col.6, lines 50-57). The system is provided by skin contact adhesive layer (col.4, lines 34-35). The matrix is silicone adhesive or acrylate adhesive (col.5, lines 15-19; col.7, lines 40-43; col.8, example 4). The reference further disclosed that gestagen is used with silicone adhesive and estrogen is used with polyacrylate adhesive (col.7, example 1; col.8, lines 35-38).

US '931 does not teach the progesterone to be Trimegestone.

US '771 teaches Trimegestone to be delivered topically to the skin (col.4, lines 34-36, 58; col.5, lines 46-49). Trimegestone is useful to treat dysmenorrheal, sterility, ovarian dystrophia, and uterine tumors and useful as contraceptive (col.4, lines 45-49).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal therapeutic system comprising two adhesive matrices, one loaded with progesterone and the other loaded with estrogen as disclosed by US '931, and replace estrogen by Trimegestone disclosed by US '771, motivated by the teaching of US '771 that Trimegestone is useful to treat dysmenorrheal, sterility, ovarian dystrophia, and uterine tumors and useful as contraceptive, with reasonable expectation of having transdermal therapeutic system that deliver Trimegestone and estrogen from two separate matrices to the patient in need of such treatment.

14. Claims 1-19 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,858,394 ('394) in view of US '771.

US '394 teaches a transdermal therapeutic system for administering a mixture of steroid sex hormones (abstract; col.1, lines 41-44). The system comprises two active ingredients containing matrix layers arranged side by side wherein one matrix is loaded with gestodene and the other is loaded with estrogen (col.5, lines 11-16, 38-45; col.8, example 4). Examples of estrogen include ethinyl estradiol (col.2, lines 10-12; col.10, line 44). The two matrices are separated by space and care must be taken for sufficient spacing of the areas to prevent a diffusion of active ingredient in the respective other

area (col.5, lines 20-23). Each matrix is covered by a separate cover layer and the system as a whole is covered by a removable protective layer (Figure 2, col.5, lines 38-45). The system is provided by skin contact adhesive layer (col.4, lines 13-14). The matrix is silicone adhesive or acrylate adhesive (col.4, lines 16-19; col.6, lines 66-67; col.8, example 4). The reference further disclosed that gestagen is used with silicone adhesive and estrogen is used with polyacrylate adhesive (col.6, example 1; col.8, lines 7-10). The reference disclosed that the individual reservoirs are provided with differing permeable polymers to adapt the diffusion flow of the individual active ingredients to the respective need (col.5, lines 23-27).

US '394 does not teach the progesterone to be Trimegestone.

US '771 teaches Trimegestone to be delivered topically to the skin (col.4, lines 34-36, 58; col.5, lines 46-49). Trimegestone is useful to treat dysmenorrheal, sterility, ovarian dystrophia, and uterine tumors and useful as contraceptive (col.4, lines 45-49).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal therapeutic system comprising two adhesive matrices, one loaded with progesterone and the other loaded with estrogen as disclosed by US '394, and replace estrogen by Trimegestone disclosed by US '771, motivated by the teaching of US '771 that Trimegestone is useful to treat dysmenorrheal, sterility, ovarian dystrophia, and uterine tumors and useful as contraceptive, with reasonable expectation of having transdermal therapeutic system that deliver Trimegestone and estrogen from two separate matrices to the patient in need of such treatment.

15. Claims 1-19 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,296,230 ('230) in view of US '771.

US '230 teaches a transdermal fertility control system comprising multi-region transdermal delivery dosage unit and method of its making (abstract). The dosage unit delivers different steroid hormones from different regions within a single dosage unit (col.16, lines 63-68). The different regions have different shapes (col.18, lines 66-68). The dosage unit contains the hormones in a matrix made of silicon adhesive polymer (col.3, lines 55-62). The reference discloses that factors can be changed to control the amount or ratio of hormones delivered from the system, and among these factors are the area and area ratio of each region, and changing the type of polymer adhesive which forms each region (col.17, lines 16-23). Hormones to be delivered by the disclosed system is combination of 17beta-estradiol and progesterone, such as megestone (col.4, lines 6-7; col.12, lines 29-30).

US '230 does not teach the progesterone to be Trimegestone.

US '771 teaches Trimegestone to be delivered topically to the skin (col.4, lines 34-36, 58; col.5, lines 46-49). Trimegestone is useful to treat dysmenorrheal, sterility, ovarian dystrophia, and uterine tumors and useful as contraceptive (col.4, lines 45-49).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal therapeutic system comprising two adhesive matrices, one loaded with progesterone and the other loaded with estrogen as disclosed by US '230, and replace estrogen by Trimegestone disclosed by US '771,

motivated by the teaching of US '771 that Trimegestone is useful to treat dysmenorrheal, sterility, ovarian dystrophia, and uterine tumors and useful as contraceptive, with reasonable expectation of having transdermal therapeutic system that deliver Trimegestone and estrogen from two separate matrices to the patient in need of such treatment.

16. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '931, US '394 and US '230 in view of US '771 as applied to claims 1-19 and 31 above, and further in view of WO93/10772 ('772).

The teachings of US '931, US '394 and US '230 each in combination with US '771 are discussed above. However, the combination of the references do not teach the species of the acrylate used with the estradiol to be 2-ethylhexyl acrylate and vinyl acetate copolymer.

WO '772 teaches transdermal delivery system to deliver 17beta-estradiol to the skin said system comprises the drug in 2-ethylhexyl acrylate and vinyl acetate copolymer matrix (abstract). The system is well-tolerated, stable, effective, prevents crystallization of the drug and ensures adequate extended level of active ingredient in the blood and has good tack and adhesive properties (pages 5 and 6).

Thus, it would have been obvious to one having ordinary skill in the art a the time of the invention to provide a transdermal drug delivery device to deliver Trimegestone and 17beta-estradiol as disclosed by the combination of the above references, and select 2-ethylhexyl acrylate and vinyl acetate copolymer matrix to deliver the estradiol,

motivated by the teaching of WO '772 that the 2-ethylhexyl acrylate and vinyl acetate copolymer matrix is well tolerated, stable, effective, prevents crystallization of estradiol and ensures adequate extended level of the hormone in the blood and has good tack and adhesive properties, with reasonable expectation of the delivered device to provide the combination of hormones from two different matrices with success.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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